Improving Process Quality and Reducing Total Expense Associated with Specimen Mislabeling in an Academic Medical Center

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Abstract

Context - Despite accreditation requirements and a focus on JCAHO patient safety goals, significant occurrence rates and multiple causes of specimen mislabeling were identified in our institution. Defect levels were ~ 0.26% of specimens received. Occurrence rates were ~200 per month.

Objective - To identify solutions, multidisciplinary workgroups were created to assess the impact of specimen mislabeling on process quality, resource utilization and patient safety.

Methods - Pathology established a Steering Committee with leaders from the laboratory, administration, nursing, risk management and quality assurance to create three task forces focusing on inpatient units, ambulatory care areas and the emergency department. A group from our Innovations in Leadership (INL) program chose specimen mislabeling as their project's focus. The INL program is designed to foster professionalism across all stakeholders in medical education.

Results - The INL workgroup compiled total charge data caused by 10 random mislabeling occurrences. After elimination of outliers, average additional charges incurred per case were $712 (n = 8) with cases from all major service areas. To raise awareness on the impact of specimen mislabeling, the INL group recommended increased use of educational techniques, marketing strategies and a bedside barcode labeling system. The Steering Committee's task forces have focused on opportunities in process and workflow. In our ED, a Failure Mode and Effects Analysis demonstrated roughly 2/3 of process risk from patient registration through specimen acquisition and order entry was associated with specimen collection and labeling. Recent improvement efforts have resulted in a 33% reduction in all mislabeled ED specimens.

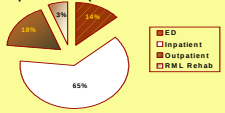
Conclusions – Early this year, the bedside barcode labeling system will be piloted and the institution will go live with a new HIS/EMR which provides computerized physician order entry. The impact of these and other changes on the status of specimen mislabeling practices continues to result in improved process, resource utilization and patient safety.

Identifying the Problem and Developing a Strategy

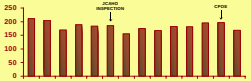
Experts estimate that up to 70% of all variability (error) in laboratory testing is preanalytical. At Loyola University Medical Center (LUMC) in late 2003, leadership in the Department of Pathology and Clinical Laboratories in conjunction with medical center leadership decided to adopt a health system-wide approach to deal with a major cause of preanalytical errors, specimen mislabeling. This focus is consistent with the 2004 and 2005 National Patient Safety Goals (NPSG) of the JCAHO, the 2004 CDC Healthcare Safety Challenges, current accreditation requirements of organizations such as the College of American Pathologists and standards of good laboratory practice. In 2005, the top JCAHO NPSG remains improving the accuracy of patient identification. The JCAHO requires that health care workers use at least two patient identifiers (neither to be the patient's room number) whenever administering medication or blood products: taking blood samples and other specimens for clinical testing or providing any other treatments or procedures. LUMC's Department of Pathology established a system-wide Steering Committee with senior representatives from the Pathology, the clinical laboratory, hospital administration, nursing administration and staff, risk management, the Center for Clinical Effectiveness (the key quality assurance department at LUMC). This group created three task forces to focus on inpatient service areas, ambulatory care areas and the emergency department (see the diagrams to the right). A fourth area, RML, the major external client for Loyola Medical Laboratories, was recognized as a comparatively minor opportunity. No task force was formed for RML. After several months of baseline monitoring, it was established that the number of all specimen mislabeling occurrences was roughly 200 per month, that this represented an overall defect level of ~0.26% of specimens received per month and that multiple causes were responsible. A monthly histogram of LUMC specimen labeling errors from that time through March, 2005, is illustrated to the right.

Specimen Labeling Steering Committee and Task Forces

Source Locations For Mislabeled Specimens (Oct 2003 – Feb 2004)



LUMC Specimen Labeling Errors Feb 2004 - March 2005



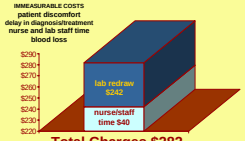
Another Multidisciplinary Group Gets Involved

Loyola University Health System (LUHS) annually conducts "***Innovations in Leadership***" (INL). The goal of the INL program is to foster professionalism across all stakeholders in medical education. INL brings together specially selected medical students, residents, nursing staff and faculty members to learn more about the skills necessary to be healthcare leaders. INL participants are grouped into teams of 8 individuals, 2 from each category, to choose a multidisciplinary team project that is important in the healthcare service mission. In spring 2004, one INL team chose specimen mislabeling for their project focus recognizing this was a challenging and system-wide problem daily involving scores of healthcare workers. They named their project "***Label Liability: Tubes on the Loose.***" The project represented a major opportunity for recommending improvement in processes that can be prone to medical error while jeopardizing patient safety. The INL team used the following assumptions:

- All occurrences were remedied in accordance with policies of the lab;
- Occurrence rates were ~ 0.26% (4.29 process sigma) of specimens received;
- Roughly 25% of the occurrences involved blood or blood product specimens;
- Low occurrence rates could still represent a significant utilization opportunity;
- Known multiple causes for the occurrences would likely require multiple strategies to improve processes in order to further reduce the rate of errors.

One INL team strategy was to compile total charge data caused by 10 random occurrences. After elimination of the lowest and highest outliers (the ~$13K ED case below), average hypothetical additional charges incurred per case were $712 (n=8) with cases from all major service areas. Although our charges were not billed, charges are a useful proxy in describing the potential of this insidious problem. Four of the cases are depicted below.

Hold That Chemo!!

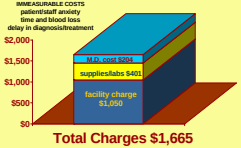


Total Charges $282

The case to the left resulted in a chemotherapy delay in the Cancer Center and later redraw in a home health patient

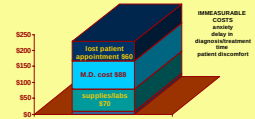
The case to the right resulted in one day's delay in an IP's discharge due to switched labels and having to wait for a test result determined to be necessary by the physician

A Tale of Two Patients



Total Charges $1,665

You Have To Do WHAT Again?



IMMEASURABLE COSTS
anxiety
delay in diagnosis/treatment time
patient discomfort

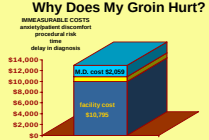
Total Charges $217

The case to the left required a repeat collection of a specimen for a microbiology test for STD

The case to the right resulted in a patient inappropriately taken to the Cath Lab on the basis of one positive and mislabeled troponin I specimen

(This case was excluded as an outlier for charge calculations)

Why Does My Groin Hurt?



Total Charges $ 12,964

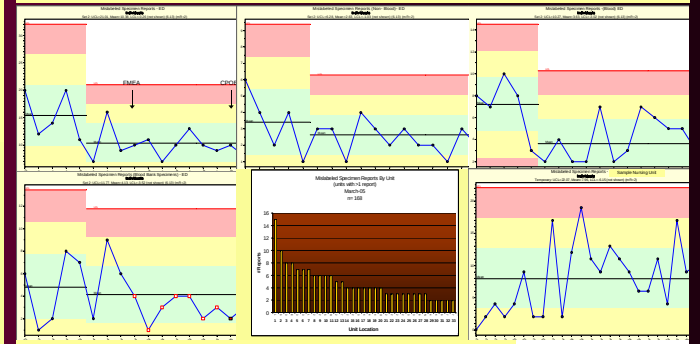
Recommendations of the INL Project Team

Using an average total of $712 per case and 200 cases per month, the annual additionally incurred charges for LUHS specimen mislabeling occurrences equals ***$1,708,800.*** To address medical errors and utilization opportunities, the INL team recommended:

- Revision of the specimen labeling protocol (Completed);
- Adding patient identification and specimen labeling questions to the yearly safety quiz competency assessment for all employees (Scheduled later in 2005);
- Educational presentation to senior leadership (Completed);
- System-wide educational/marketing campaign using "***Speci-Man"*** (Postponed due to CPOE start);
- Use of bedside barcode specimen labeling systems (Pilot rescheduled to new unit for summer 2005).

Activities in Progress

Work of the Specimen Labeling Steering Committee and Task Forces continues to focus on the same key process issues identified by the INL team: accountability, awareness, communication, simplification, savings and error reduction. Although system-wide implementation of CPOE has postponed some relevant QI activities, improving specimen labeling is a system-wide priority for continued efforts. In mid-2004, A Failure Mode Effects Analysis (FMEA) was conducted in the ED. The FMEA demonstrated that roughly 2/3 of process risk from patient registration through specimen acquisition and order entry was associated with specimen collection and labeling. As a result, several actions were taken. Process improvement efforts have resulted in a 33 % reduction in all mislabeled specimens. Impact of the FMEA on ED specimens (total), blood specimens, non-blood specimens and blood bank specimens is shown below. Occurrences by nursing unit are tracked and shared (also shown below). The pilot location for the bedside barcode specimen labeling system will be in a high occurrence service unit.



Next Steps and Summary

High priority next steps regarding specimen mislabeling at LUHS are planned:

- Identify and assess the impact system-wide of CPOE on these processes;
- Pilot use of the bedside barcode labeling system in a high occurrence area;
- Evaluate the impact of this pilot. If indicated, develop a broader strategy for implementation;
- Conduct FMEA on providing blood/blood products to key units such as OR;
- Revise safety quiz/competency assessments to highlight these issues;
- Determine effective approach for further education and marketing strategies;
- Decrease targets for defect rate at 75% reduction from baseline;
- Reduce occurrences below 50 per month (i.e., 1 – 2 per day).

This is part of the annual quality plan of the Pathology Department. A defect reduction rate of < 50 occurrences per month would raise the process sigma level to ~ 4.8 while, theoretically, reducing associated costs and incurred charges by ~75%. Although the varied causes for specimen mislabeling at LUHS were not categorized here, our task forces continue to assess patterns and location-specific issues. While there are reports on the significance of proper specimen labeling, reports on strategies and solutions to mislabeling are isolated and anecdotal. We were unable to find any comparable occurrence rates reported or defect reduction targets established by other institutions or benchmarking programs. Multiple strategies to address multiple causes appears to be an appropriate approach. Retaining the focus on accountability, awareness, communication, simplification, savings and error reduction is consistent with the overall patient safety and quality focus of LUHS.